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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/518,949

12/17/2004

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EXAMINER

LILLING, HERBERT J

ART UNIT

PAPER NUMBER

1657

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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31 DAYS

02/22/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

# Office Action Summary

Application No.

10/518,949

Applicant(s)

STREEKSTRA ET AL.

Examiner

HERBERT J. LILLING

Art Unit

1657

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on December 17, 2004 (Preliminary Amd).
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-15 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

1. Receipt is acknowledged of the following papers:

- a) Statement pertaining to a deposited strain CBS 168.95 filed December 17, 2004;
- b) Certified copy of the foreign document as well as certified copy of English translation filed December 17, 2004;
- c) Preliminary amendment filed December 17, 2004, which includes amendment to claims that includes new claims 12-15;

and

- d) Information disclosure statement filed April 22, 2005;
- for this Application which is a 371 of PCT EP03/06552 filed June 20, 2003 which claims benefit to three EP documents:

2002EP-02254262.5      June 19, 2002

2002EP-02258713.3      December 18, 2002

2003EP-03251169.3      February 26, 2003

2. Claims 1-15 are now present in this application.

3. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

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Group I, claim(s) 1, drawn to a process for the production of a PUFA, which includes a-g.

Claims 2-6 will be examined with this invention.

Group II, claim(s) 7, drawn to a microbial oil which comprises at least 50% arachidonic acid (ARA) and: a) has at least a 90% triglyceride content; b) has a peroxide value (POV) of no more than 2.5; c) has an anisidine value (AnV) of no more than 1.0; d) is hexane extracted; and/or e) has a phospholipid content below 5%.

Claims (8-9) will be examined with this invention.

Group III, claim 10, drawn to a composition comprising a microbial oil obtained by the process of according to claim 1.

Claims 11-15 will be examined with this invention.

4. The inventions are independent or distinct, each from the other because:

Inventions I and II/III are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product as claimed can be made by another and materially different process.

Invention II does not require the specifics of Invention I.

Invention III does not require the specifics of Invention II.

The prior art of record clearly indicates that groups of inventions are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In addition, because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions require a different field of search (see MPEP § 808.02), and because the inventions have acquired a separate status in the art due to their recognized divergent subject matter which require different computerized searches and examination for the distinct products which lack the same common single general concept under PCT Rules, thus the restriction for examination purposes as indicated is proper.

5. This application contains claims directed to the following patentably distinct species:

A. Whereby process for the production of a PUFA requires:

i. the item ( c ) only

1. whereby the carbon source is rate limiting on the growth of the micro-organisms,

2. whereby the carbon source is restricted such that the micro-organisms metabolise fat(s) and/or lipid(s),

3. combination of above;

ii. the items (d) and (e) requires only :

1. the rate of addition of the carbon source is reduced

2. the rate of addition of the carbon source is below the rate of consumption of the carbon source by the micro-organisms

3. the carbon source has been all used,

4. the carbon source has a concentration in the medium of about zero, at or before the end of fermentation

5. combination of the above – please specify.

iii. item (f) and (g) which requires only:

1. the carbon source addition is stopped but fermentation is allowed to continue,

2. the micro-organisms are subjected to conditions whereby they metabolise, or consume, one or more fat(s) or lipids(s) in preference to arachidonic acid (ARA).

3. combination of 1 and 2.

iv. whereby the above processes i. –iii. Stage precedes the end of the fermentation:

1. precedes the end of fermentation starts at from 15 to 2 hours before the end of the fermentation ,

2. or less than 10 days after the beginning of the fermentation.

v. Whereby the culture medium:

1. requires an additive oil;

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2. does not require an additive oil.

vi. Whereby the process requires

1. PUFA comprising ARA,

2. vessel having a capacity of at least 10 liters,

3. combination of the above.

vii. Whereby the microorganism is

1. Mortierella,

a. species *Mortierella alpina*,

b. other species-please specify;

2. Other genus – please specify.

B. Whereby the composition is:

a. obtainable by a process according to claim 1,

which composition is:

1. foodstuff,

2. food,

3. feed,

4. feed supplement,

5. pharmaceutical,

6. veterinary,

7. cosmetic.

Further, claim 11 is drawn to an infant formula which claim is improper since there is no antecedent basis for this claim.

- b. A composition comprising a microbial oil of claim 7.
- c. Claim 14 improper claim which cannot be examined.
- d. Claim 15 improper claim which cannot be examined.

6. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, no claim is generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).



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7. Applicant is advised that the reply to this requirement to be complete must include (i) an election of an invention I, II or III and an election of species for each of A-[i. through vii.] and B [a through d] to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

9.

**F.P.: Ochiai/Brouwer Rejoinder form paragraph**

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

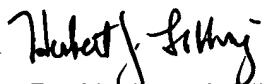
10. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

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11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Lilling whose telephone number is 571-272-0918 and Fax Number is **571-273-8300**, or SPE Jon Weber whose telephone number is 571-272-0925. Examiner can be reached Monday-Friday from about 7:30 A.M. to about 7:00 P.M. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Art Unit **1657**  
February 14, 2007



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